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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/808,522

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Wei Liu

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EXAMINER

SWOPE, SHERIDAN

ART UNIT

PAPER NUMBER

1656

DATE MAILED: 05/26/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/808,522

Applicant(s)

LIU ET AL

Examiner

Sheridan L. Swope

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-47 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-47 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |  |
|---|--|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)            |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date ____ | 6) <input type="checkbox"/> Other: ____  |

### **DETAILED ACTION**

Claims 1-47 are pending.

#### ***Election/Restrictions***

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-18 and 44-46, drawn to a polynucleotide encoding a kinase polypeptide, classified in class 536, subclass 23.2.
- II. Claims 19, 20, and 47, drawn to a kinase polypeptide, classified in class 435, subclass 194.
- III. Claims 21 and 22, drawn to an antibody to a kinase polypeptide, classified in class 530, subclass 389.1.
- IV. Claims 23 and 24, drawn to a non-human transgenic animal comprising a polynucleotide encoding a kinase polypeptide, classified in class 800, subclass 8.
- V. Claims 25-28, drawn to a method of inhibiting apoptosis using a polynucleotide encoding a kinase polypeptide, classified in class 514, subclass 44.
- VI. Claims 29-34, drawn to a method for identifying modulators of a kinase polypeptide, classified in class 435, subclass 15.
- VII. Claims 37 and 38, in part, 35 and 36, drawn to a method of treatment using a modulator of a kinase polypeptide, classified in class 514, subclass 1.
- VIII. Claim 37, in part, drawn to a method of treatment to enhance the expression of a polynucleotide encoding a kinase polypeptide, classified in class 514, subclass 1.
- IX. Claim 38, in part, drawn to a method of treatment to inhibit the activity of a kinase polypeptide, classified in class 514, subclass 1.

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- X. Claims 38, in part, 39-43, drawn to a method of inhibiting expression of a polynucleotide encoding a kinase polypeptide using an inhibitory nucleic acid molecule, classified in class 514, subclass 44.

For each of Inventions I-X above, restriction to one of the following is also required under 35 USC 121. Therefore, election is required of one of Inventions I-X and one or more of Inventions (A)-(B), as indicated.

For any one of Inventions I-X, elect one of:

(A) SEQ ID NO: 1/encoding SEQ ID NO: 2 or SEQ ID NO: 2

(B) SEQ ID NO: 4/encoding SEQ ID NO: 5 or SEQ ID NO: 5

Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). Also, product and process inventions are distinct if any of the following can be shown: (1) that the process as claimed can be used to make another and materially different product, (2) that the product claimed can be used in a materially different process of using that product, or (3) that the product claimed can be made by another and materially different process (MPEP § 806.05(h)). These inventions are different or distinct for the following reasons.

The polynucleotide of Invention I is related to the polypeptide of Invention II by virtue of encoding the same. The DNA molecule has utility for the recombinant production of the polypeptide in host cells. Although the DNA molecule and polypeptide are related, since the DNA encodes the specifically claimed polypeptide, they are distinct inventions because they are physically and functionally distinct chemical entities, and the polypeptide product can be made

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by another and materially different process, such as by synthetic peptide synthesis or purification from the natural source. Further, the DNA may be used for processes other than the production of the polypeptide, such as in a nucleic acid hybridization assay.

The protein of Invention II is related to the antibody of Invention III by virtue of being the cognate antigen necessary for the production of antibodies. Although the protein and antibody are related, due to the necessary steric complementarity of the two, they are distinct inventions because they are physically and functionally distinct chemical entities and because the protein can be used in another and materially different process from the use for production of the antibody, such as in a pharmaceutical composition in its own right.

Inventions I and III are unrelated because the products of Inventions I and III are physically and functionally distinct chemical entities.

Inventions I and IV are distinct because the products of Inventions I and IV are physically and functionally distinct chemical entities.

Inventions II and IV are unrelated because the products of Inventions II and IV are physically and functionally distinct chemical entities.

Inventions III and IV are unrelated because the products of Inventions III and IV are physically and functionally distinct chemical entities.

Inventions V-X are independent because the methods of Inventions V-X comprise different steps, utilize different products and/or produce different results.

The polynucleotide of Invention I is related to the methods of Inventions V and X as a product and process of using. The inventions are distinct because the polynucleotide can also be used for making the encoded protein.

Invention I is unrelated to Inventions VI-IX because the methods of Inventions VI-IX can neither use the polynucleotide of Invention I nor be used to make said polynucleotide.

The polypeptide of Invention II is related to the method of Invention VI as a product and process of using. The inventions are distinct because the polypeptide can also be used for making an antibody.

Invention II is unrelated to Inventions V and VII-X because the methods of Inventions V and VII-X can neither use the polypeptide of Invention II nor be used to make said polypeptide.

Invention III is unrelated to Inventions V-X because the methods of Inventions V-X can neither use the antibody of Invention III nor be used to make said antibody.

Invention IV is unrelated to Inventions V-X because the methods of Inventions V-X can neither use the transgenic animal of Invention IV nor be used to make said transgenic animal.

A search for more than one of Inventions I-X would be a burden on the Office for the following reasons.

The search of Invention I would not encompass a search for Invention II, which would include searching the prior art for teachings of the purified polypeptide. Conversely, a search for Invention II, class 435, subclass 194, would not encompass a search for Invention I, which would include searching class 536, subclass 23.2. Thus, a search of either Invention I or II would not encompass a search for the other invention and searching both inventions would be a burden on the Office.

Because the products of Inventions I and III are structurally and/or functionally distinct entities, a search for one said invention would not encompass a search for any other invention and searching all of Inventions I and III would be a burden on the Office.

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Because the products of Inventions I and IV are structurally and/or functionally distinct entities, a search for one said invention would not encompass a search for any other invention and searching all of Inventions I and IV would be a burden on the Office.

The search of Invention II would not encompass a search for invention III, which would include searching the prior for teachings of the naturally-occurring antibody. Conversely, a search for Invention III, class 530, subclass 389.1, would not encompass a search for Invention II, which would include searching class 435, subclass 194. Thus, a search of either Invention II or III would not encompass a search for the other invention and searching both inventions would be a burden on the Office.

Because the products of Inventions II and IV are structurally and/or functionally distinct entities, a search for one said invention would not encompass a search for any other invention and searching all of Inventions II and IV would be a burden on the Office.

Because the products of Inventions III and IV are structurally and/or functionally distinct entities, a search for one said invention would not encompass a search for any other invention and searching all of Inventions III and IV would be a burden on the Office.

Because the methods of Inventions V-X comprise different steps, utilize different products, and/or produce different results, a search for one said invention would not encompass a search for any other invention and searching all of Inventions V-X, or a subset thereof would be a burden on the Office.

A search for the products of Inventions I-IV would not encompass a search for the methods of Inventions V-X, or vice versa, because said methods are not the only methods of

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making and/or using said products. Thus, a search of any of Inventions I-IV with any of Inventions V-X would be a burden on the Office.

These inventions are distinct for the reasons given above and have acquired a separate status in the art due to their recognized divergent subject matter, as shown by their different classification. Furthermore, as explained above, searching more than one invention would be a burden on the Office. Therefore, restriction for examination purposes, as indicated, is proper.

Restriction between product and process claims has been required. Where Applicant elects claims directed to a product, and the product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the Official Gazette notice dated March 26, 1996 (1184 O.G. 86; see also M.P.E.P. 821.04, *In re Ochiai*, and *In re Brouwer*). Process claims that depend from or otherwise include all the limitations of the patentable product will be entered as a matter of right, if the amendment is presented prior to final rejection or allowance, whichever is earlier. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. To be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).



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To insure that each document is properly filed in the electronic file wrapper, it is requested that each of amendments to the specification, amendments to the claims, Applicants' remarks, requests for extension of time, and any other distinct papers be submitted on separate pages.


It is also requested that Applicants identify support, within the original application, for any amendments to the claims and specification.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sheridan L. Swope whose telephone number is 571-272-0943. The examiner can normally be reached on M-F; 9:30-7 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen Kerr can be reached on 571-272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published application may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on the access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Sheridan Lee Swope, Ph.D.  
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**SHERIDAN SWOPE, PH.D.**  
**PRIMARY EXAMINER**